534 Rec'd PCT/PTC 25 JUL2000

FORM PTO-1390 (REV 10-95) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER: IVD 1025

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

U. S. APPLICATION NO. (If known, see 37 CFR 1.5): 09/600968

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/FR99/00098	20 January 1999	26 January 1998

TITLE OF INVENTION: DIETETIC COMPOSITION IN THE FORM OF A SUBSTITUTION SALT FOR TABLE SALT

APPLICANT(S) FOR DO/EO/US

DERRIEN, Marcel and FONTVIEILLE, Anne-Marie

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND or SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1)).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371 (c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An executed oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
    Citation of References

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
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17. ☒ The following fees are submitted:

	CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1. 492 (a)(1)-(5)):		
Search Report has been prepared by the EPO or JPO. $840.00		
International preliminary examination fee paid to USPTO (37CFR 1.482) $670.00		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) $760.00		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO $970.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4). $96.00		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 840.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ]20 [ ]30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	23- 20 =	3	x $18.00	$ 54.00	
Independent claims	1 - 3 =	0	x $78.00		
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ $260.00	$	
TOTAL OF ABOVE CALCULATIONS =				$ 894.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				$	
SUBTOTAL =				$ 894.00	
Processing fee of **$130.00** for furnishing the English translation later than [ ]20 [ ]30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +				$	
TOTAL NATIONAL FEE =				$ 894.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ 40.00	
TOTAL FEES ENCLOSED =				$ 934.00	
				Amount to be refunded:	$
				Charged	$934.00

a. ☐ A check in the amount of $_____ to cover the above fees is enclosed.

b. ☒ Please charge my Deposit Account No. **19-0091** in the amount of **$934.00** to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **19-0091**. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Paul E. Dupont
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SIGNATURE 25 July 00 DATE

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Filing under 35 U.S.C. § 371
Corresponding to International
Application Serial No.: PCT/FR99/00098

Applicants: Marcel DERRIEN and
Anne-Marie FONTVIEILLE

International Filing Date: 20 January 1999

For: DIETETIC COMPOSITION IN THE FORM OF A SUBSTITUTION SALT FOR TABLE SALT

CERTIFICATE UNDER 37 C.F.R. 1.10

Express Mail Label Number: EL301242593US

Date of Deposit: July 25, 2000

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service on the date indicated above and is addressed to: Asst. Commissioner for Patents, Box PCT, Attn: EO/US, Washington, DC 20231.

Paula L. Ackley

Signature

Assistant Commissioner for Patents
Box PCT
Attn: EO/US
Washington, D.C. 20231
Dear Sir:

PRELIMINARY AMENDMENT

Please amend the above-identified application as follows:

In the specification:

At page 7, line 21 immediately preceeding "salting" insert - - substantially equivalent or even greater - - and following "power" delete "substantially equal to or even higher than it".

In the Claims:

Please cancel claims 2-13, and add new claims 14-35 before calculating the filing fee for the above-identified application.

Please amend claim 1 as follows:

1. (Amended). [Dietetic] A dietetic composition in the form of a salt substitute for table salt[, characterized in that it comprises] comprising, by weight, from:

40% to 50% of potassium chloride,

15% to 25% of sodium chloride,

15% to 25% of one or more calcium salts, and

8% to 15% of one or more magnesium salts

[and optionally from:

0.5% to 2.5% of one or more antiagglomerating agents

0.5% to 2.5% of one or more taste-enhancing agents].

Please add the following new claims 14-35.

- - 14. A dietetic composition according to claim 1 additionally comprising from 0.5% to 2.5% by weight of one or more antiagglomerating agents.

15. A dietetic composition according to claim 1 additionally comprising from 0.5% to 2.5% by weight of one or more taste-enhancing agents.

16. A dietetic composition according to claim 15 additionally comprising from 0.5% to 2.5% by weight of one or more antiagglomerating agents.

17. A dietetic composition according to claim 14 comprising from 0.5% to 1% by weight of one or more antiagglomerating agents.

18. A dietetic composition according to claim 15 comprising from 0.5% to 2% by weight of one or more taste-enhancing agents.

19. A dietetic composition according to claim 18 additionally comprising from 0.5% to 1% by weight of one or more antiagglomerating agents.

20. A dietetic composition according to claim 1 comprising, by weight, from:

45% to 50% of potassium chloride,

15% to 20% of sodium chloride,

15% to 20% of one or more calcium salts, and

10% to 15% of one or more magnesium salts.

21. A dietetic composition according to claim 20 additionally comprising from 0.5% to 1% by weight of one or more antiagglomerating agents.

22. A dietetic composition according to claim 20 additionally comprising from 0.5% to 2% by weight of one or more taste-enhancing agents

23. A dietetic composition according to claim 22 additionally comprising from 0.5% to 1% by weight of one or more antiagglomerating agents.

24. A dietetic composition according to claim 23, wherein the calcium salt is selected from the group consisting of monocalcium phosphate, dicalcium phosphate, tricalcium phosphate, calcium glycerophosphate, calcium dicitrate and calcium D-gluconate.

25. A dietetic composition according to claim 24, wherein the magnesium salt is selected from the group consisting of a magnesium phosphate, magnesium gluconate and dibasic magnesium citrate.

26. A dietetic composition according to claim 25, wherein the calcium salt is monocalcium phosphate.

27. A dietetic composition according to claim 26, wherein the magnesium salt is dibasic magnesium citrate.

28. A dietetic composition according to claim 27, wherein at least one antiagglomerating agent is selected from the group consisting of magnesium carbonate, colloidal silica, magnesium silicate, stearic acid, magnesium stearate and a calcium phosphate.

29. A dietetic composition according to claim 28, wherein at least one taste-enhancing agent is selected from the group consisting of glutamic acid, calcium glutamate, magnesium glutamate, ascorbic acid, calcium ascorbate, magnesium ascorbate, citric acid, calcium citrate and magnesium citrate.

30. A dietetic composition according to claim 29, additionally containing 0.01% by weight of potassium iodide.

31. A dietetic composition according to claim 29 comprising by weight:
45% of potassium chloride,
20% of sodium chloride,
20% of monocalcium phosphate,
12% of dibasic magnesium citrate,
1% of magnesium carbonate,
1% of ascorbic acid, and
1% of glutamic acid.

32. A method for increasing the dietary supply of magnesium and calcium which comprises utilizing in place of common table salt a composition according to claim 1.

33. A method for increasing the dietary supply of magnesium and calcium which comprises utilizing in place of common table salt a composition according to claim 31.

34. A method for the treatment of mild or gravidic high blood pressure, the prevention of high blood pressure, the correction of magnesium deficiencies and/or the treatment or prevention of hydrosodium retention, which comprises utilizing in place of common table salt a composition according to claim 1.

35. A method for the treatment of mild or gravidic blood pressure, the prevention of high blood pressure, the prevention of high blood pressure, the correction of magnesium deficiencies and/or the treatment or prevention of hydrosodium retention which comprises utilizing in place of common table salt a composition according to claim 31. - -

REMARKS

No new matter is added by the amendments of the specification and claim 1 or by new claims 14-35.

The text at page 7, lines 21-22 of the specification has been rewritten in more appropriate grammatical form and claim 1 has been amended to put it in appropriate U.S. claim format.

Amended claim 1 and new claims 14-16 correspond to original claim 1 in which neither of, one of, or both of the optional elements are recited. Likewise, new claims 17-19 and 20-23 correspond to original claims 2 and 3 respectively.

New claims 24, 25 and 28-30 correspond to original claims 4, 5 and 8-10 respectively but depend only from the immediately preceding claim rather than from all preceeding claims.

New claims 26 and 27 correspond to original claims 6 and 7 respectively.

New claim 31 corresponds to original independent claim 11 written in dependent form.

Original use claim 12, which depended from all preceding claims, has been replaced by new claims 32 and 33, which depend from claims 1 and 31 respectively.

Likewise, original use claim 13, which depended from claims 1-11, has been replaced by new claims 34 and 35, which depend from claim 1 and 31 respectively.

The application as presently amended contains claims 1 and 14-35.

Respectfully submitted,

Date: 25 July 02

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ENGLISH TRANSLATION OF INTERNATIONAL PATENT
APPLICATION PCT/FR99/00098
filed on 20 January 1999

CERTIFICATE UNDER 37 C.F.R. 1.10

Express Mail Label No.: EL301242593US

Date of Deposit: July 25, 2000

I hereby certify that the attached English Translation is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" Service on the date indicated above, and is addressed to:
Asst. Commissioner for Patents, Box PCT, Attn: EO/US, Washington, DC 20231

Paula S. Deckey
Signature

"Dietetic composition in the form of a salt substitute for table salt"

The present invention relates in general to a dietetic composition in the form of a salt substitute for common table salt.

In particular, the invention relates to a dietetic composition in the form of a low-sodium substitute salt which is useful as a supplement in the case of mild or moderate high blood pressure.

The benefit of a pharmacological correction of high blood pressure on the risk of cardiovascular complications has been clearly demonstrated.

Thus, a decrease in blood pressure of 6 mm Hg causes a reduction in the risk of cerebrovascular accidents and of myocardial infarction of 42 and 14%, respectively.

For this reason, a nonpharmacological approach has been generally recommended in the case of high blood pressure at least in the initial phase of the management of a mild or even moderate hypertension, or in combination with a drug treatment.

This attitude is motivated by the abundant literature which shows a statistical or even physiopathological relationship between certain factors and high blood pressure. Thus, nicotine addiction, excessive alcohol consumption, being overweight,

certain dietary imbalances relating to the supply of sodium, potassium, calcium and magnesium, stress and sedentary lifestyle are implicated as factors or cofactors in the onset, maintenance or worsening of hypertension.

The results of numerous studies tend to show the important role of mineral salts in the regulation of blood pressure: sodium is thought to increase this pressure whereas the opposite appears to be demonstrated for potassium and magnesium.

Indeed, epidemiological studies suggest an inverse relationship between the dietary supply of K^+ ion and the prevalence of high blood pressure.

A meta-analysis published in JAMA: 1997; 277: 1624-1632 and relating to 33 studies in fact reports that oral supplementation with potassium is associated with a reduction of 3.11 mm Hg for systolic pressure and 1.97 mm Hg for diastolic pressure. The hypotensive effect would, in addition, appear to be more marked in subjects who have a higher sodium consumption.

Thus, it appears demonstrated that an additional supply of K^+ ion could decrease blood pressure.

In populations used to a diet high in potassium, the incidence of cerebrovascular accidents in fact appears to be low.

Furthermore, it has been shown that a provoked depletion of potassium, of short duration, aggravates a preexisting hypertension and induces an increase in blood pressure in volunteers with normal blood pressure. Among the numerous mechanisms invoked, the most important appears to be the natriuretic effect of the K^+ ion, which would explain the poor response obtained during additional supplies of potassium in persons under sodium restriction.

Numerous studies have shown, moreover, a more marked relationship of the Na^+/K^+ ratio with blood pressure than with Na^+ or K^+ alone. The result is that the dietetic measures for reducing blood pressure appear to be more effective when the supplies of different mineral salts are changed simultaneously.

Thus, following intervention studies, it appears reasonable to encourage a diet high in potassium or to have recourse to supplementation.

Moreover, an additional supply of magnesium is likewise recommended in hypertensives. This recommendation is based on observations which were initially carried out in rats where a magnesium deficiency causes the appearance of a marked hypertension.

Furthermore, the Mg^{++} ion, a natural vasodilator antagonist of the Ca^{++} ion at numerous

levels, constitutes a cofactor for numerous enzymes and its deficient presence could produce haemodynamic deteriorations and ventricular arrhythmias.

Recently, it has in fact been demonstrated that the Mg^{++} ion, administered in the acute phase of myocardial infarction reduces the onset of arrhythmias and mortality.

An additional supply of magnesium is in addition indicated during resistant hypokaliemia generally due to a hypomagnesemia. This supplementation can in fact be tried for a few weeks without any major risk when a deficiency is identified or is highly suspected.

Furthermore, the benefit of a simultaneous additional supply of potassium and magnesium with a decrease in the supply of sodium in particular for a decrease in blood pressure has been clearly demonstrated.

For example, a study carried out over 24 weeks in elderly persons with a moderate hypertension has been published in British Medical Journal 1994; 309: 436-440.

Following this study, it has been possible to show that the replacement of common table salt (sodium chloride) with a salt containing 41% of sodium chloride, 41% of potassium chloride, 17% of magnesium

salts and 1% of minerals in trace amounts causes a reduction of 7.6 mm Hg in systolic pressure and of 3.3 mm Hg in diastolic pressure.

These results lead to the conclusion that a substitute salt low in Na^+ ion but enriched with K^+ ion and with Mg^{++} ion offers an advantageous nonpharmacological approach for reducing mild to moderate hypertension.

This trial, like others also published (Circulation Supplement, 1996, vol. 94, No. 8, p. 1983) suggest, consequently, that the replacement of common table salt with a salt low in Na^+ ion but, on the other hand, high in K^+ and Mg^{++} ions could be of interest as therapeutic adjuvant in particular in the treatment of moderate hypertension.

Numerous other compositions useful as substitute salts have been proposed in order to reduce the daily supply of Na^+ ion.

Among these are in particular substitute salts with a reduced sodium content but enriched with potassium and magnesium in substantial quantities.

To this effect, there may be mentioned:

a) patent GB 2015803 which describes a substitute salt containing, by weight of the composition, 50 to 65% of NaCl, 20 to 40% of KCl or K_2SO_4 and 5 to 20% of $MgCl_2$ or $MgSO_4$,

b) patent US 4473595 which reports a substitute salt containing, by weight of the composition, 40 to 50% of NaCl, 25 to 35% of KCl and 15 to 25% of $MgCl_2$ or $MgSO_4$.

However, salt substitutes for table salt including sodium, potassium, magnesium and calcium salts are also known and have been published.

However, the magnesium salts and calcium salts are present therein in relatively low quantities.

There may be mentioned, to this effect:

c) patent US 4107346 where a replacement composition for table salt is described which comprises Na^+, K^+, Mg^{++} and Ca^{++} ions, in proportions substantially corresponding to those present in the extracellular fluids of the human body, these proportions comprising, by weight, 92 to 93.1% of Na^+ ion; 2.4 to 3.4% of K^+ ion; 3.1 to 3.4% of Ca^{++} ion; 1.2 to 1.4% of Mg^{++} ion.

d) patent GB 2237720 which cites a dietetic salt consisting of sea salt or rock salt enriched with KCl, that is to say having a final composition comprising, by weight, 46.6% of NaCl; 6.5% of $MgCl_2$; 2.8% of $MgSO_4$; 2.2% of $CaSO_4$; 41.5% of KCl; 0.10% of $MgBr_2$ and 0.2% of $CaCO_3$.

e) patent EP 0291578 which describes a table salt substitute containing 40 to 85% by weight of rock salt, 5 to 45% by weight of KCl, 2 to 10% by weight of

of $CaCO_3$ and 2 to 10% by weight of $MgCO_3$.

It will be observed, however, that in each of the substitute salts of the state of the art reported above, sodium chloride remains present in an amount of at least 40% by weight, that is to say in a relatively large quantity.

The search for a salt substitute for common table salt, comprising potassium chloride, a magnesium salt as well as sodium chloride, itself in a quantity by weight proportionally lower than in the previous compositions, this substitute salt having, furthermore, acceptable taste qualities and salting power, remains of paramount interest.

Now, it has been found, surprisingly, that by partially replacing, with calcium salts, the sodium chloride of the substitute salts of the prior art, it is possible to obtain compositions which can be used as dietetic supplements in mild or moderate hypertension while possessing at the same time a taste which is quite similar to that of common table salt and a salting power substantially equal to or even higher than it.

The subject of the present invention is therefore a dietetic composition, in the form of a salt substitute for table salt, comprising by weight, from:

40% to 50% of potassium chloride

15% to 25% of sodium chloride

15% to 25% of one or more calcium salts

8% to 15% of one or more magnesium salts.

As calcium salt, a phosphate, that is to say monocalcium phosphate, dicalcium phosphate, tricalcium phosphate or calcium glycerophosphate, is advantageously used. This calcium salt may also be calcium dicitrate or calcium D-gluconate.

However, monocalcium phosphate, that is to say $Ca(H_2PO_4)_2$, is preferred.

Likewise, the magnesium salt may be a magnesium phosphate, magnesium gluconate or dibasic magnesium citrate. The latter is in fact preferably used in the dietetic compositions according to the invention.

It is observed, in addition, that the calcium or magnesium salts present in the dietetic compositions according to the invention, in particular monocalcium phosphate and dibasic magnesium citrate possess taste qualities which are generally superior to those of calcium lactate, chloride or hydroxide or alternatively magnesium chloride or sulphate.

To allow them ease of flow and without formation of agglomerates, the compositions according to the invention will contain, if necessary, one or more antiagglomerating agents in an amount of 0.5% to

2.5% by weight of the total composition, in particular 0.5% to 1% by weight of this composition.

Magnesium carbonate is normally used as antiagglomerating agent.

However, other agents of this type, such as colloidal silica, magnesium silicate, stearic acid, magnesium stearate or a calcium phosphate can be advantageously envisaged.

Furthermore, the dietetic compositions according to the invention may optionally contain one or more taste-enhancing agents, in an amount of 0.5% to 2.5% by weight of the total composition, in particular from 0.5% to 2% by weight of this composition. This taste enhancer, which contributes in particular to the masking of the bitterness of the K^+ ion and to the impression of saltiness, is preferably glutamic acid, a glutamate such as calcium glutamate or magnesium glutamate, ascorbic acid, an ascorbate such as calcium ascorbate or magnesium ascorbate, citric acid or a citrate such as calcium citrate or magnesium citrate.

If necessary, the dietetic compositions according to the invention may include traces of an iodinated compound, preferably potassium iodide, in order to obtain an iodinated substitute salt. This iodinated compound, and preferably potassium iodide, is normally added in an amount of about 0.01% by weight of

the final composition.

According to a particular and preferred aspect, the invention relates to a dietetic composition in the form of a salt substitute for table salt, comprising, by weight, from:

45% to 50% of potassium chloride

15% to 20% of sodium chloride

15% to 20% of one or more calcium salts

10% to 15% of one or more magnesium salts

and optionally from:

0.5% to 1% of one or more antiagglomerating agents

0.5% to 2% of one or more taste-enhancing agents.

The dietetic compositions according to the invention have proved to be free of after taste and of bitter taste and their use as condiment or a source of seasoning gives a perception of a taste similar to that of table salt or sodium chloride.

In addition, in spite of their low content of sodium chloride, the dietetic compositions according to the invention, through their completely advantageous salting power, could reduce by at least 60% the daily consumption of Na^+ ion.

Compared with the substitute salts of the state of the art, the dietetic compositions according to the invention are mainly characterized by the replacement of a certain proportion by weight of sodium

chloride with an equivalent proportion of one or more calcium salts.

These calcium salts not only confer on the compositions according to the invention completely acceptable taste qualities but significantly contribute to controlling mild or moderate hypertension.

Indeed, it is known that the increase in the dietary supply of calcium reduces blood pressure and favourably affects the arterial function of the smooth muscle in different forms of experimental hypertension.

Thus, the dietetic compositions according to the invention, in the form of salt substitutes for table salt, can be advantageously used to increase the supply of magnesium and calcium. In this regard, they are particularly advantageous from the nutritional point of view. These supplies are often insufficient in subjects with mild or moderate high blood pressure.

The subject of the present invention is also the use of a composition as defined above or below as adjuvant in the treatment of mild or gravidic high blood pressure, in the prevention of high blood pressure, in the correction of magnesium deficiencies, in the prevention or treatment of hydrosodium retention or alternatively in persons wishing to reduce their consumption of common table salt. The composition claimed is in particular useful for the preparation of

a pharmaceutical composition useful for the treatment of mild or gravidic high blood pressure, the prevention of high blood pressure, the correction of magnesium deficiencies and/or the prevention or treatment of hydrosodium retention.

Sensory analyses have been carried out in order to determine the mean value of iso-salty concentrations of a substitute salt according to the invention having the formulation by weight:

potassium chloride	45%
sodium chloride	20%
monocalcium phosphate	20%
dibasic magnesium citrate	12%
magnesium carbonate	1%
ascorbic acid	1%
glutamic acid	1%

and this being compared with table salt. "Iso-salty concentration" is understood to mean the concentration of the substitute salt according to the invention which gives the same salty intensity in the mouth as a reference solution of table salt.

These results have then made it possible to calculate the salting power of this substitute salt represented by the ratio between the concentration of the reference solution and the mean value of the iso-salty concentrations determined during several trials.

a) Iso-salty concentration in mashed potato

The so-called "up-and-down" method is used to this effect whose benefit is to make it possible to very rapidly obtain a correct estimation of the salting intensity of a solution or of a food compared with a solution or with a reference food containing a given concentration of table salt (NaCl).

This method consisted in presenting, to a group of 27 experienced and trained tasters, stimuli of increasing or decreasing intensity according to the responses of the subjects.

A protocol was used to this effect similar to that of a test of classifying in pairs, each pair consisting of a variable stimulus (substitute salt of the invention) and a constant reference (table salt).

In the above test, there is used as reference a mashed potato containing 0.6 g of table salt (NaCl)/100 g of mashed potato and as variable stimulus a range of 8 decreasing concentrations of the substitute salt of the invention, from a maximum concentration of 4 g/100 g of mashed potato with a decreasing step of 1.5.

Consequently, the concentrations of substitute salt were 4 g/100 g; 2.67 g/100 g; 1.77 g/100 g ; 1.18 g/100 g; 0.79 g/100 g; 0.53 g/100 g; 0.35 g/100 g; 0.23 g/100 g; 0.16 g/100 g.

During the tests, the mashed potatoes were kept hot in yoghurt machines. In addition, the experimenters operated binomially, one experimenter being a taster, the other a tester, and then the roles were reversed.

On each presentation of the pairs to be tasted, the taster experimenter should assess which of the two mashed potatoes was the more salty.

A mean value of iso-salty concentrations of 0.33 g/100 g of mashed potato was thus found.

In other words, on average 0.33 g of substitute salt was needed in 100 g of mashed potato to confer the same salty taste intensity as 0.6 g of table salt in 100 g of mashed potato.

b) Salting power in the mashed potato

The salting power detected by a subject corresponds to the ratio of the reference concentration to the mean value of the iso-salty concentrations whereas the salting power detected by the group of experimenters is equal to the mean of the salting powers obtained for each subject.

In the above test, the salting power of the substitute salt detected by the group of experimenters was 2.07.

In conclusion, the salting power of the substitute salt of the invention in the mashed potato

is quite remarkable given its low content of sodium chloride (20% by weight).

Taken in this food, the substitute salt could reduce by 90% the sodium chloride supplies while allowing a coverage of 28% of the recommended daily supplies of Mg^{++} ion and of 45% of the recommended daily supplies of Ca^{++} ion for 5 g of daily consumption.

The dietetic compositions according to the invention can be prepared by mixing, after calibration, the different ingredients entering into the formulation so as to obtain a homogeneous mixture free of segregation.

The following nonlimiting example illustrates the preparation of such a dietetic composition of the invention.

EXAMPLE

A dietetic composition of the invention is prepared which has the formula:

potassium chloride	45%
sodium chloride	20%
monocalcium phosphate	20%
dibasic magnesium citrate	12%
magnesium carbonate	1%
ascorbic acid	1%
glutamic acid	1%

by application of the following method:

All the ingredients entering into the composition are weighed and premix is prepared, over 5 minutes and with stirring (24 revolutions/min) on an inverting mixer. The premix is then calibrated on a grid with a mesh opening of 0.8 mm and it is again mixed, with stirring (24 revolutions/min), for 20 minutes.

The mixture obtained is taken up by calibrating it on a grid with a mesh opening of 0.5 mm and then the final mixing is carried out, with stirring (24 revolutions/min), for 15 minutes.

CLAIMS

1. Dietetic composition in the form of a salt substitute for table salt, characterized in that it comprises, by weight, from:

40% to 50% of potassium chloride

15% to 25% of sodium chloride

15% to 25% of one or more calcium salts

8% to 15% of one or more magnesium salts

and optionally from:

0.5% to 2.5% of one or more antiagglomerating agents

0.5% to 2.5% of one or more taste-enhancing agents.

2. Dietetic composition according to Claim 1, characterized in that it comprises, by weight, from:

0.5% to 1% of one or more antiagglomerating agents

0.5% to 2% of one or more taste-enhancing agents.

3. Dietetic composition according to Claim 1 or 2, characterized in that it comprises, by weight, from:

45% to 50% of potassium chloride

15% to 20% of sodium chloride

15% to 20% of one or more calcium salts

10% to 15% of one or more magnesium salts

and optionally from:

0.5% to 1% of one or more antiagglomerating agents

0.5% to 2% of one or more taste-enhancing agents.

4. Dietetic composition according to one of Claims 1 to 3, characterized in that the calcium salt is monocalcium phosphate, dicalcium phosphate, tricalcium phosphate, calcium glycerophosphate, calcium dicitrate or calcium D-gluconate.

5. Dietetic composition according to one of Claims 1 to 4, characterized in that the magnesium salt is a magnesium phosphate, magnesium gluconate or dibasic magnesium citrate.

6. Dietetic composition according to Claim 4, characterized in that the calcium salt is monocalcium phosphate.

7. Dietetic composition according to Claim 5, characterized in that the magnesium salt is dibasic magnesium citrate.

8. Dietetic composition according to one of Claims 1 to 7, characterized in that it comprises, in addition, at least one antiagglomerating agent chosen from magnesium carbonate, colloidal silica, magnesium silicate, stearic acid, magnesium stearate and a calcium phosphate.

9. Dietetic composition according to one of Claims 1 to 8, characterized in that it comprises, in addition, at least one taste-enhancing agent chosen from glutamic acid, calcium glutamate, magnesium glutamate, ascorbic acid, calcium ascorbate, magnesium

ascorbate, citric acid, calcium citrate and magnesium citrate.

10. Dietetic composition according to one of Claims 1 to 9, characterized in that it contains, in addition, 0.01% by weight of potassium iodide.

11. Dietetic composition in the form of a salt substitute for table salt, characterized in that it comprises, by weight:

45% of potassium chloride

20% of sodium chloride

20% of monocalcium phosphate

12% of dibasic magnesium citrate

1% of magnesium carbonate

1% of ascorbic acid

1% of glutamic acid.

12. Use of a dietetic composition according to one of Claims 1 to 11 for increasing the supply of magnesium and calcium.

13. Use of a composition as defined in Claims 1 to 11 for the preparation of a pharmaceutical composition useful for the treatment of mild or gravidic high blood pressure, the prevention of high blood pressure, the correction of magnesium deficiencies and/or the treatment or prevention of hydrosodium retention.

PATENT APPLICATION

for:

"DIETETIC COMPOSITION IN THE FORM OF A SALT SUBSTITUTE FOR TABLE SALT"

in the name of:

SANOFI

Invention by: Marcel DERRIEN and Anne-Marie FONTVIEILLE

ABSTRACT OF THE TECHNICAL CONTENT OF THE INVENTION

The present invention relates to a dietetic composition in the form of a salt substitute for table salt, characterized in that it comprises, by weight, from:

40% to 50% of potassium chloride

15% to 25% of sodium chloride

15% to 25% of one or more calcium salts

8% to 15% of one or more magnesium salts.

Fig. none.

1025
915

Docket No. 1025A/DC

DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION

__X__ Original _____ Supplemental _____ Substitute

As a below-named inventor, I hereby declare that:

My residence, citizenship and post office address are given below under my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

DIETETIC COMPOSITION IN THE FORM OF A SUBSTITUTION SALT FOR TABLE SALT

the specification of which

____ is attached hereto.

____ was filed on _____ as United States
Application Serial No. _____
and was amended on _____ (if applicable).

__X__ was filed on 20 January 1999 as PCT International
Application No. PCT/FR99/00098
and was amended under PCT Article 19 on _____ (if applicable).

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge my duty to disclose information of which I am aware which is material to the examination of this application in accordance with Section 1.56 of Title 37 of the Code of Federal Regulations.

I hereby claim foreign priority benefit under Section 119 (a) - (d) of Title 35 of the United States Code of any foreign application(s) for patent or inventor's certificate or of any PCT application(s) designating at least one country other than the United States identified below and also identify below any foreign application(s) for patent or inventor's certificate or any PCT application(s) designating at least one country other than the United States filed by me on the same subject matter and having a filing date before that of the application(s) from which priority is claimed:

			Priority Claimed	
Country	Number	Filing Date	Yes	No
France	98 00800	26 January 1998	X	

I hereby claim benefit under Section 120 of Title 35 of the United States Code of any United States application(s) or PCT application(s) designating the United States identified below and, insofar as the subject matter of each of the claims of this application is not disclosed in said prior application(s) in the manner provided by the first paragraph of Section 112 of Title 35 of the United States Code, I acknowledge my duty to disclose material information of which I am aware as defined in Section 1.56 of Title 37 of the Code of Federal Regulations which occurred between the filing date of the prior application(s) and the national or PCT filing date of this application:

Application Serial No.	Filing Date	Status

I hereby appoint Michael D. Alexander, Reg. No. 36,080; and Paul E. Dupont, Reg. No. 27,438, or any of them my attorneys or agents with full power of substitution and revocation to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein and in the above-identified specification of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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